K093591

SECTION 4

DEC – 3 2009

SECTION 4 – 510(k) SUMMARY

[As required by 21CFR807.92]

4.1 Date Prepared [21CFR807.92(a)(1)]

May 11, 2009

4.2 Submitter's Information [21CFR807.92(a)(1)]

Company Name:	XAVANT TECHNOLOGY (PTY) LTD
Street Address:	Ravello 1st Floor, Delmondo Office Park 169 Garsfontein Road Ashlea Gardens 0081
City:	Pretoria
State/Province:	Gauteng
Country:	South Africa
Telephone:	+27(0) 12 755 9491
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Contact Person:	Brian Rothman
Contact Title:	Quality Assurance and Regulatory Compliance Officer
Contact Email:	brian@xavant.com

4.3 Trade Name, Common Name, Classification [21CFR807.92(a)(2)]

Trade Name:	STIMPOD NMS400 Nerve Stimulator
Common Name:	Battery Powered Peripheral Nerve Stimulator
Classification Name:	Battery Powered Nerve Stimulator per 21 CFR § 868.2775
Device Class:	Class II
Product Code:	BXN

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4.4 Identification of Predicate Device(s) [21CFR807.92(a)(3)]

PREDICATE DEVICES
HDC Corporation, NeuroTrace III (K023342)
Xavant Technology, XPOD/XMAP Nerve Stimulator (K072092)
Stockert GmbH, Stimuplex HNS12 (K052313)

There are no significant differences between the STIMPOD NMS400 Nerve Stimulator and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

4.5 Description of the Device [21CFR807.92(a)(4)]

The STIMPOD NMS400 is a battery powered peripheral nerve stimulators that can be used for

- nerve mapping using the non-invasive Nerve Mapping Probe (supplied)
- nerve locating using invasive electrodes/needles (not supplied)

The stimulus is generated by a constant current source. The waveform is a square wave with various pulse width options.

The anode comprises of an ECG electrode (not supplied). The cathode comprises a permanently attached nerve mapping probe (supplied), and/or a separate nerve locating needle (not supplied), depending on the mode of the unit.

4.6 Intended Use [21CFR807.92(a)(5)]

This product is a nerve stimulation device designed to be used by an anesthetist during regional anesthesia for the purpose of

1. nerve mapping using the non-invasive Nerve Mapping Probe (supplied) and
2. nerve locating using invasive electrodes/needles (not supplied)

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4.7 Technological Characteristics [21CFR807.92(a)(6)]

Stimulus Modes

Monophasic Square wave, repeating at 1Hz or 2Hz

Current Ranges

Nerve mapping:	0 – 20mA
Pulse Width:	0.05ms, 0.1ms, 0.3ms, 0.5ms, 1ms
Nerve Locating:	0.0 – 5.0mA
Pulse Width:	0.05ms, 0.1ms, 0.3ms, 0.5ms, 1ms

Stimulation Voltages

Nerve Mapping:	Max 300V p-p
Nerve Locating:	Max 100V p-p

Waveform

Constant Current

Monophasic

Squarewave

Nerve Mapping Probe

Nerve Mapping Probe designed for non-invasive nerve mapping

Technical Specifications

Power Supply	4 x AAA Alkaline Batteries
Weight	130g
Dimensions	145mm x 90mm x 30mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Xavant Technology Party, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-5926

DEC - 3 2009

Re: K093591
Trade/Device Name: STIMPOD NMS400 Nerve Stimulator
Regulation Number: 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: October 26, 2009
Received: November 19, 2009

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K093591

Device Name: **STIMPOD NMS400 Nerve Stimulator**

Indications for Use:

This product is a nerve stimulation device designed to be used by an anesthetist during regional anesthesia for the purpose of

1. nerve mapping using the non-invasive Nerve Mapping Probe (supplied) and
2. nerve locating using invasive electrodes/needles (not supplied)

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093591